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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROGER JOHN DALY and ROBERT L. SUTHERLAND

Appeal 2008-2123
Application 09/509,196
Technology Center 1600

Decided: May 21, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 5-7, 19-22, 24-29, and 31-41, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

Claim 22 is illustrative:

An isolated polynucleotide molecule comprising a nucleotide sequence having at least 95% sequence identity to that shown in SEQ ID NO:1.

The Examiner relies on the following prior art references to show unpatentability:

D. Stein et al., "The SH2 domain protein GRB-7 is co-amplified, overexpressed and in a tight complex with HER2 in breast cancer," 13(6) *The EMBO Journal* 1331-1340 (1994).

Roger J. Daly et al., "Cloning and Characterization of *GRB14*, a Novel Member of the *GRB7* Gene Family," 271(21) *J. Biol. Chem.* 12502-12510 (1996).

Tatsuya Kishi et al., "Molecular Cloning of Human GRB-7 Co-amplified with *CAB1* and c-*ERBB-2* in Primary Gastric Cancer," 232 *Biochem. Biophys. Res. Comm.* 5-9 (1997).

Shinji Tanaka et al., "Coexpression of Grb7 with Epidermal Growth Factor Receptor or Her2/erbB2 Human Advanced Esophageal Carcinoma," 57 *Cancer Research* 28-31 (1997).

Roger J. Daly, "The Grb7 Family of Signalling Proteins," 10(9) *Cell. Signal.* 613-618 (1998).

B. C. Baguley et al., "In vitro modeling of human tumour behavior in drug discovery programmes," 40 *Eur. J. Can.* 794-801 (2004).

The rejections as presented by the Examiner are as follows:

Claims 5-7, 19-22, 24-29, and 31-41 stand rejected under 35 U.S.C. § 101 as lacking utility and § 112, first paragraph, for lack of enablement based on the finding of lack of utility.

We reverse.

DISCUSSION

Findings of Fact (FF):

1. SEQ ID NO: 1 encodes “a polypeptide comprising an amino acid sequence substantially corresponding to that shown as SEQ ID NO: 2” (Spec. 3: 1-13).
2. SEQ ID NO: 1 encodes a “candidate effector protein for the Grb7 family of signaling proteins” (Spec. 3: 1-3).
3. The protein of SEQ ID NO: 2 is designated 2.2412 (Spec. 2: 33-34);
4. “Grb7 family proteins exhibit differential expression in certain human cancers (particular breast and prostate cancer) and may therefore be involved in tumour progression” (Spec. 5: 13-15).
5. “Detection of the protein encoded by the cDNA 2.2412 in a sample should provide a useful tumour marker and/or prognostic indicator for these cancers” (Spec. 5: 15-17).
6. The Hitoshi Declaration establishes that subsequent to the filing date of Appellants’ Specification 2.2412 “has been reported to be a tumor-specific antigen as evidenced by the detection of . . . antibodies [to the protein] in sera of breast cancer patients” (Decl. 3: ¶ 10).

The Examiner finds that the 2.2142 protein is an orphan protein and that Appellants’ have not disclosed “a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect” (Ans. 4). We disagree. *See* FF 1-6.

The Examiner finds that Appellants' Specification "fails to provide any evidence or sound scientific reasoning to allow a conclusion that the instant 2.2412 protein encoded by the claimed polynucleotides is associated with any type of cancer, including prostate or breast cancer" (Ans. 6). We disagree.

Appellants' Specification discloses that the detection of the protein encoded by the cDNA 2.2412 in a sample should provide a useful tumour marker and/or prognostic indicator for, *inter alia*, breast cancer (FF 4-5). In this regard, we note that Appellants' Specification is presumed to be an accurate disclosure of the claimed invention. *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971). Further, the Hitoshi Declaration establishes that subsequent to the filing date of Appellants' Specification 2.2412 "has been reported to be a tumor-specific antigen as evidenced by the detection of . . . antibodies [to the protein] in sera of breast cancer patients" (FF 6). Post filing date evidence can be used to verify the accuracy of a statement already in the Specification. *In re Brana*, 51 F.3d 1560, 1567 n. 19 (Fed. Cir. 1995).

For the foregoing reasons we are not persuaded by the Examiner's reliance on Stein's 1994 publication which, according to the Examiner, teaches that the determination of whether Grb-7 expression "has prognostic significance in patients with primary breast cancer remains to be seen" (Ans. 12). Further, as Appellants' Specification makes clear, the prior art between Stein's publication date and the filing date of the instant application established a link between GRB7 overexpression and human breast cancer (Spec. 2:25-30).

We are not persuaded by the Examiner's reliance on Baguley and Daly '96 to teach that cells lines may not be predictive of primary cancer

tissue. The preponderance of the evidence of record weighs in favor of a finding that the 2.2412 protein is a tumor-specific antigen (FF 5-6). Further, contrary to the Examiner's intimation (Ans. 14), we do not find that the Kishi and Tanaka references detract from a finding that the 2.2412 protein is a tumor-specific antigen in breast cancer (*see* FF 5-6).

For the foregoing reasons we reverse the rejection of claims 5-7, 19-22, 24-29, and 31-41 stand rejected under 35 U.S.C. § 101. The rejection under the enablement provision of 35 U.S.C. § 112 is a corollary to the rejection under 35 U.S.C. § 101 and is reversed for the same reasons set forth above.

CONCLUSION

In summary, we reverse the rejections of record.

REVERSED

Ssc:

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